
ISR Number: 6030080 Case Number: 6878422 I/F Code: I Report Date: 20090105
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010959563
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS AS NEEDED ONCE/TWICE A DAY PO
Event Date: 20090105
FDA Date: 20090106
Follow Number:
Image ID: 6030080-1
Age: 31 YR Gender: F Weight: 250 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start: 20081231
Therapy End: 20081215
Duration:
Adverse Reactions:
 ANGER
 DRUG INEFFECTIVE
 ECONOMIC PROBLEM
 PRODUCT QUALITY ISSUE

ISR Number: 6037263 Case Number: 6880743 I/F Code: I Report Date: 20090114

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010984814

Mfg. Date: 20090112

Mfg. Number: A0763019A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP5303

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1PUFF AS REQUIRED

Event Date:

FDA Date: 20090114

Follow Number:

Image ID: 6037263-5

Age: 69 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End: 20040101

Duration:

Adverse Reactions:

- CARDIAC ABLATION
- CARDIAC DISORDER
- COUGH
- HEART RATE INCREASED
- PALPITATIONS
- THROAT TIGHTNESS

ISR Number: 6044068 Case Number: 6886700 I/F Code: I Report Date: 20090120
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011009380
Mfg. Date: 20090116
Mfg. Number: A0763989A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20090120
Follow Number:
Image ID: 6044068-8
Age: 59 YR Gender: M Weight: 70 KG
Occupation: CN
Country: CANADA
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
AGGRESSION
DIZZINESS
FEELING ABNORMAL
MALAISE
SPEECH DISORDER

ISR Number: 6056672 Case Number: 6899092 I/F Code: I Report Date: 20090115
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011052379
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP9994
Expiration Date: 20100101
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1 SPRAY 10 TIMES PER DAY 2 DAYS
Event Date: 20090115
FDA Date: 20090126
Follow Number:
Image ID: 6056672-1
Age: 51 Gender: Weight: 193 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start:
Therapy End: 20090115
Duration:
Adverse Reactions:
 DEVICE INEFFECTIVE
 DRUG INEFFECTIVE
 PRODUCT QUALITY ISSUE

ISR Number: 6059039 Case Number: 6896923 I/F Code: I Report Date: 20090130

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1011060396

Mfg. Date: 20090119

Mfg. Number: B0554711A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNSPECIFIED

Expiration Date:

Indication: ASTHMATIC CRISIS

Route: RESPIRATORY (INHALATION)

Dose:

Event Date: 20080824

FDA Date: 20090130

Follow Number:

Image ID: 6059039-5

Age: 57 YR Gender: F Weight:

Occupation: CN

Country: FRANCE

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ABDOMINAL PAIN UPPER
- DYSPNOEA
- EJECTION FRACTION DECREASED
- ELECTROCARDIOGRAM ABNORMAL
- HEPATOCELLULAR INJURY
- NAUSEA
- OVERDOSE
- STRESS CARDIOMYOPATHY
- ULTRASOUND SCAN ABNORMAL
- VOMITING

ISR Number: 6059081 Case Number: 6896965 I/F Code: I Report Date: 20090130

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011060622

Mfg. Date: 20090122

Mfg. Number: B0556608A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number:

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: ORAL

Dose:

Event Date: 20090104

FDA Date: 20090130

Follow Number:

Image ID: 6059081-4

Age: 2 YR Gender: M Weight:

Occupation: PH

Country: ISRAEL

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- ACCIDENTAL OVERDOSE
- DRUG ADMINISTRATION ERROR
- INCORRECT ROUTE OF DRUG ADMINISTRATION
- PALPITATIONS
- PRODUCT QUALITY ISSUE

ISR Number: 6061562 Case Number: 6904012 I/F Code: I Report Date: 20090129
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011069275
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 5445
Expiration Date: 20091231
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1 INHALATION 1 INHAL
Event Date: 20090129
FDA Date: 20090130
Follow Number:
Image ID: 6061562-4
Age: 36 YR Gender: F Weight: 198 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: N
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20090129
Therapy End: 20090129
Duration:
Adverse Reactions:
PRURITUS
SWOLLEN TONGUE
TONGUE DISORDER

ISR Number: 6071021 Case Number: 6905203 I/F Code: I Report Date: 20090209

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011104527

Mfg. Date: 20090202

Mfg. Number: B0556959A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 5133

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF AS REQUIRED

Event Date: 20090127

FDA Date: 20090209

Follow Number:

Image ID: 6071021-0

Age: 56 YR Gender: F Weight:

Occupation: CN

Country: UNITED KINGDOM

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End: 20090127

Duration:

Adverse Reactions:

- ASTHMA
- HEART RATE INCREASED
- INSOMNIA

ISR Number: 6078533 Case Number: 6918883 I/F Code: I Report Date: 20090211

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011131504

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 8ZP8975

Expiration Date: 20100101

Indication: ASTHMA

Route: ORAL

Dose: 108MCG 2 EVERY 4-6 HOURS PO

Event Date: 20090210

FDA Date: 20090212

Follow Number:

Image ID: 6078533-4

Age: 23 YR Gender: F Weight: 131 LBS

Occupation:

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:

Therapy Start:

Therapy End:

Duration: 1 DAY

Adverse Reactions:

- CHEST PAIN
- COUGH
- DRUG INEFFECTIVE
- DYSPNOEA
- PRODUCT QUALITY ISSUE
- WHEEZING

ISR Number: 6083101 Case Number: 6920444 I/F Code: I Report Date: 20090202
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011147915
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose: 2 PUFFS EVERY 4 HRS
Event Date: 20090118
FDA Date: 20090213
Follow Number:
Image ID: 6083101-4
Age: Gender: M Weight: 130 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20090119
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE

ISR Number: 6086047 Case Number: 6920903 I/F Code: I Report Date: 20090216
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011158892
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP0829
Expiration Date: 20091031
Indication: ASTHMA
Route:
Dose: EVERY 4/6 HOURS PRN INHAL EVERY
Event Date: 20090213
FDA Date: 20090217
Follow Number:
Image ID: 6086047-0
Age: 56 Gender: F Weight: 179 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: Rechallenge Code: Y Death Date:
Therapy Start: 20090215
Therapy End: 20090101
Duration:
Adverse Reactions:
ABDOMINAL DISCOMFORT
ASTHMA
CONDITION AGGRAVATED
DRUG EFFECT DECREASED
HYPERSENSITIVITY
RASH

ISR Number: 6087447 Case Number: 6923598 I/F Code: I Report Date: 20090217
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011164733
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 5446
Expiration Date: 20091231
Indication: ASTHMA
Route:
Dose: MANY PUFFS Q5 MIN INHAL
Event Date: 20090217
FDA Date: 20090218
Follow Number:
Image ID: 6087447-5
Age: 38 YR Gender: F Weight: 200 LBS
Occupation: OT
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20090217
Therapy End: 20090217
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 PRODUCT QUALITY ISSUE

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ISR Number: 6088526 Case Number: 6926354 I/F Code: I Report Date: 20090219
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011168392
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20091231
Indication: ASTHMA
Route: ORAL
Dose: 2 PUFFS AS NEEDED PO
Event Date: 20090216
FDA Date: 20090220
Follow Number:
Image ID: 6088526-9
Age: 3 YR Gender: F Weight: 32 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20090201
Therapy End: 20051201
Duration:
Adverse Reactions:
DENTAL CARIES
TOOTH EROSION

ISR Number: 6088981 Case Number: 6924342 I/F Code: I Report Date: 20090204
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011169769
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP0329
Expiration Date: 20091224
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: INHALE 1 PUFF EVERY 4 HOURS AS NEEDED
Event Date: 20090129
FDA Date: 20090220
Follow Number:
Image ID: 6088981-4
Age: 59 YR Gender: F Weight:
Occupation: PH
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: LT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20090204
Therapy End: 20090129
Duration:
Adverse Reactions:
COUGH
DEVICE FAILURE
PRODUCT QUALITY ISSUE
WHEEZING

ISR Number: 6119544 Case Number: 6941764 I/F Code: I Report Date: 20090316
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011282370
Mfg. Date: 20090306
Mfg. Number: B0541382A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: 7051
Expiration Date:
Indication: ASTHMA
Route: ORAL
Dose:
Event Date: 20081002
FDA Date: 20090316
Follow Number:
Image ID: 6119544-X
Age: Gender: F Weight: 60 KG
Occupation: PH
Country: AUSTRALIA
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20081002
Duration:
Adverse Reactions:
ANXIETY
PALPITATIONS
TREMOR

ISR Number: 6121489 Case Number: 6948040 I/F Code: I Report Date: 20090312
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011289907
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP5531
Expiration Date: 20091031
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 2 INHALATIONS AS NEEDED INHAL
Event Date: 20090228
FDA Date: 20090313
Follow Number:
Image ID: 6121489-6
Age: 51 YR Gender: F Weight:
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y
Outcome Code: OT Dechallenge Code: N Rechallenge Code: D Death Date:
Therapy Start: 20090228
Therapy End: 20090101
Duration:
Adverse Reactions:
 DRUG INEFFECTIVE
 THERAPEUTIC RESPONSE UNEXPECTED WITH DRUG SUBSTITUTION

ISR Number: 6124335 Case Number: 6951765 I/F Code: I Report Date: 20090317
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011301629
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route:
Dose:
Event Date:
FDA Date: 20090318
Follow Number:
Image ID: 6124335-X
Age: Gender: Weight:
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
NO THERAPEUTIC RESPONSE

ISR Number: 6128314 Case Number: 6948756 I/F Code: I Report Date: 20090323

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011316805

Mfg. Date: 20090317

Mfg. Number: A0773623A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: 8ZP0495

Expiration Date:

Indication: BRONCHOSPASM

Route: RESPIRATORY (INHALATION)

Dose: 2PUFF FOUR TIMES PER DAY

Event Date: 20090129

FDA Date: 20090323

Follow Number:

Image ID: 6128314-8

Age: 60 YR Gender: F Weight:

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start: 20090205

Therapy End: 20090129

Duration: 1 WK

Adverse Reactions:

- DIZZINESS
- SUFFOCATION FEELING
- SYNCOPE
- VOMITING

ISR Number: 6129633 Case Number: 6956869 I/F Code: I Report Date: 20090320

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011321531

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 PUFF AS NEEDED INHAL

Event Date: 20090107

FDA Date: 20090323

Follow Number:

Image ID: 6129633-1

Age: 28 YR Gender: F Weight: 130 LBS

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: LT Dechallenge Code: Y Rechallenge Code: D Death Date:

Therapy Start: 20090107

Therapy End: 20090107

Duration:

Adverse Reactions:

ANXIETY

ASTHMA

CONDITION AGGRAVATED

PALPITATIONS

PRODUCT QUALITY ISSUE

TACHYCARDIA

TREMOR

VOMITING

ISR Number: 6132103 Case Number: 6951820 I/F Code: I Report Date: 20090325
Drug Name: **VENTOLIN**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1011331198
Mfg. Date: 20090319
Mfg. Number: A0774013A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number: 8ZP5303
Expiration Date:
Indication: RESPIRATORY TRACT CONGESTION
Route: RESPIRATORY (INHALATION)
Dose: 1PUFF UNKNOWN
Event Date: 20090318
FDA Date: 20090325
Follow Number:
Image ID: 6132103-8
Age: 55 YR Gender: M Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End: 20090316
Duration:
Adverse Reactions:
LOSS OF CONSCIOUSNESS

ISR Number: 6133493 Case Number: 6955748 I/F Code: I Report Date: 20090324

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011336422

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number:

Expiration Date:

Indication: ASTHMA

Route:

Dose: 1 OR 2 PUFFS 4 TO 6 HOURS INHAL

Event Date: 20090322

FDA Date: 20090325

Follow Number:

Image ID: 6133493-2

Age: 49 YR Gender: F Weight: 147 LBS

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: OT Dechallenge Code: D Rechallenge Code: Y Death Date:

Therapy Start: 20090324

Therapy End: 20090322

Duration:

Adverse Reactions:

- DRUG HYPERSENSITIVITY
- NO THERAPEUTIC RESPONSE
- PARAESTHESIA
- PRURITUS
- STRESS

ISR Number: 6141239 Case Number: 6962659 I/F Code: I Report Date: 20090327

Drug Name: **VENTOLIN**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1011368914

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 8ZP4697

Expiration Date: 20091031

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 1 PUFF 2X A DAY INHAL

Event Date: 20081120

FDA Date: 20090330

Follow Number:

Image ID: 6141239-7

Age: 43 YR Gender: F Weight: 119 LBS

Occupation:

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:

Therapy Start:

Therapy End:

Duration: 2 MON

Adverse Reactions:

- ASTHMA
- CONDITION AGGRAVATED
- DRUG EFFECT DECREASED
- DRUG HYPERSENSITIVITY
- HYPERTENSION
- LOSS OF CONSCIOUSNESS
- PRODUCT QUALITY ISSUE